Reducing Amputation Rates in Patients With Diabetes at a Military Medical Center

The Limb Preservation Service model

VICKIE R. DRIVER, DPM, MS, FACFAS
JEFF MADSEN, MS, CRC
RUSSELL A. GOODMAN, BS, PHD, CAN

OBJECTIVE — To describe and evaluate the Limb Preservation Service (LPS), a multidisciplinary, state-of-the-art, foot care clinic for patients with diabetes at Madigan Army Medical Center (MAMC). Evaluation criteria include the overall incidence of lower-extremity amputation (LEA) and the distribution of the anatomic level of amputation between 1999 and 2003.

RESEARCH DESIGN AND METHODS — This is a retrospective study of the incidence and types of LEAs performed in patients with diabetes at MAMC. Patients with diagnosed diabetes and LEA procedures were identified by ICD-9-Clinical Modification (CM) codes. Hospital and clinic characteristics that are integral to the success of the program are described.

RESULTS — The number of patients at MAMC with diagnosed diabetes increased 48% from 1999 to 2003; however, the number of LEAs decreased 82% from 33 in 1999 to 9 in 2003. Amputations of the foot, ankle, and toe comprise 71% of amputations among patients with diabetes.

CONCLUSIONS — The results of this study provide evidence of the value of a focused multidisciplinary foot care program for patients with diabetes. Associations between the creation of the LPS and LEA rates are discussed.

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The prevalence of diabetes in the U.S. is currently 6.3%, or 18.2 million people (2002), which includes ~5.2 million undiagnosed people. Type 2 diabetes is increasing in the U.S. for a number of reasons. The current obesity epidemic tops the list, along with an aging population. The prevalence of diagnosed diabetes has doubled between 1990 and 2002 from 6.7 million to 13.3 million (1). Diabetes is the leading nontraumatic cause of amputation in the U.S. In 1997, the total number of lower-extremity amputations (LEAs) for diabetic patients in the U.S. peaked at 84,000, excluding military health care facilities, and the total figure has remained >80,000 annually since that time (2).

Foot ulcers precede ~85% of LEAs in patients with diabetes (3,4). The 1-year incidence of new ulcers in patients with diabetes in the U.S. ranges from 1.0 to 2.6% (5–8). The annual incidence of LEA for patients with diabetes varies from 3.6 to 13.7 per 1,000 patients (8–12). The 3-year mortality rate after a diabetic LEA is between 35 and 50% (8).

In the U.S., the Healthy People 2010 objectives include a 55% reduction in LEA frequency and annual foot examinations for at least 75% of patients with diabetes (13). Internationally, the 1989 World Health Organization and International Diabetes Foundation–sponsored St. Vincent's Declaration mandated a 50% reduction in diabetic LEAs (14,15).

Direct costs for diabetic LEAs in the U.S. range from $22,700 for a toe amputation, to $51,300 for an above-the-knee amputation in 2001 dollars (16). A comprehensive analysis of LEA costs in Sweden in 1995, including inpatient, outpatient, home, and rehabilitation care for patients who healed after LEA, showed a cost of $43,100 for a minor amputation and $63,100 for a major amputation (17).

This article describes and evaluates the Limb Preservation Service (LPS), a multidisciplinary, state-of-the-art, diabetic foot care clinic at the Madigan Army Medical Center (MAMC). Evaluation criteria include the incidence and distribution of LEAs among diabetic patients between 1999 and 2003. Examination procedures and treatment protocols for the LPS will be illustrated and explained. We describe characteristics of the clinic, including the advantages of a large military hospital setting, the extensive patient and practitioner education programs, a diverse clinical research program, and the paradigm of evaluation and treatment comprising the LPS model.

From the Department of Orthopedics, Limb Preservation Service, Madigan Army Medical Center, Tacoma, Washington.

Address correspondence and reprint requests to Vickie R. Driver, DPM, MS, FACFAS, Madigan Army Medical Center, ATT: Department of Orthopedics, Limb Preservation Service, 9040A Fitzsimmons Ave., Tacoma, WA 98431. E-mail: vickie.driver@nw.amedd.army.mil.

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Abbreviations: CDC, Centers for Disease Control and Prevention; LEA, lower-extremity amputation; LPS, Limb Preservation Service; MAMC, Madigan Army Medical Center.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

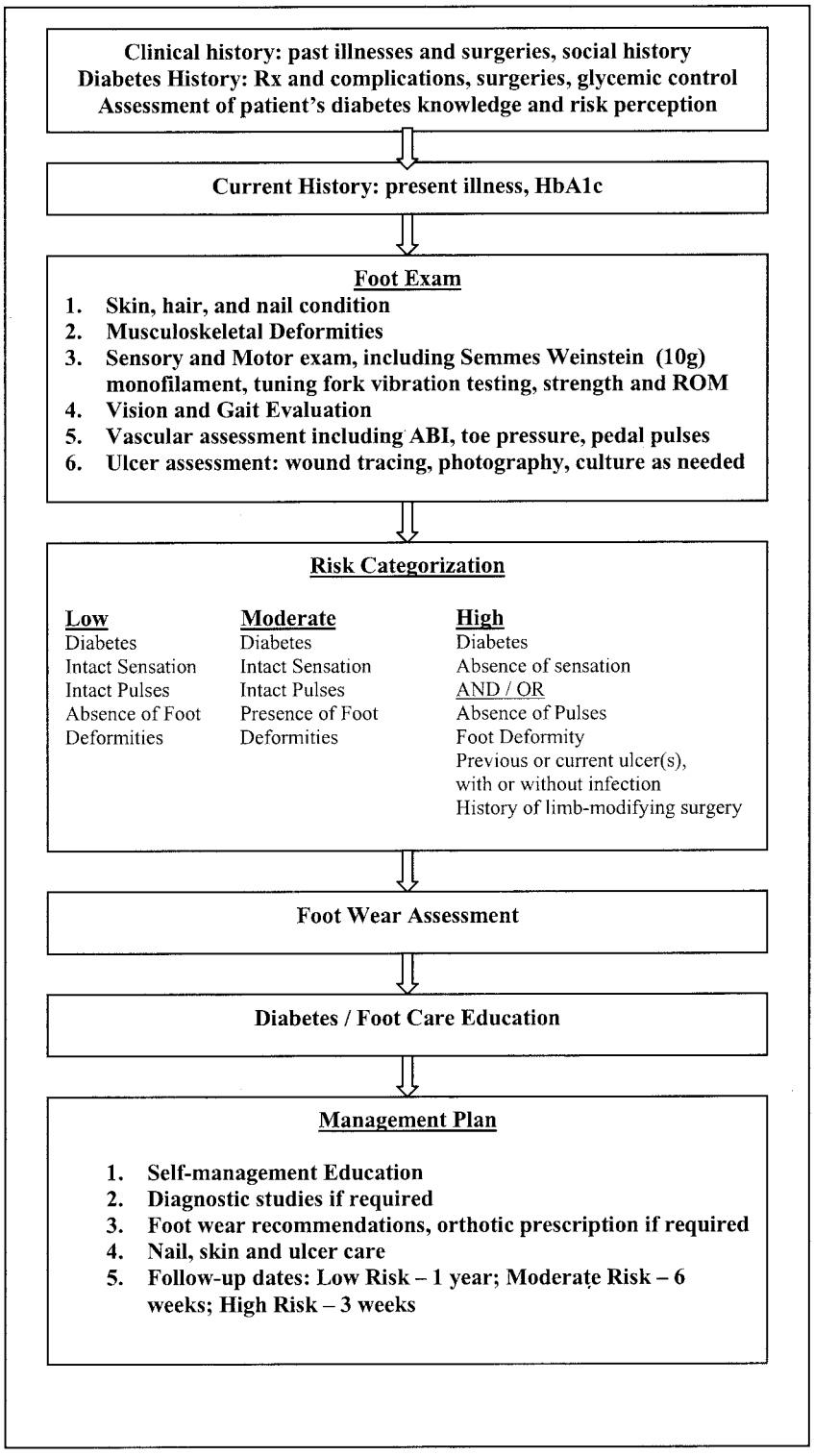

Figure 1—*Foot examination components.*

RESEARCH DESIGN AND METHODS

— MAMC, at Fort Lewis, Washington, treats ~350,000 individuals across a six-state region. More than 120,000 soldiers, family members, and retirees reside within 40 miles of the hospital. In 2003, MAMC treated 4,940 enrolled patients with diagnosed diabetes, an increase of 48% from 1999. Some patients may seek care at other armed forces medical centers, and MAMC treats patients whose care is based elsewhere. The migration of patients is assumed to be balanced over time. MAMC is the only armed forces medical center of its type in the northwest U.S.; therefore, patient attrition is assumed to be less than in civilian healthcare, where similar facilities and specialists are often available in one area.

Concern over the rate of LEA in diabetic patients prompted the establishment of a specialized foot care clinic at MAMC in 1995. Previously, patients with diabetic foot ulcers were followed by physicians from many specialties at MAMC. Since the initiation of the clinic now known as the LPS, high-risk diabetic foot care has become a focused specialty providing standard and advanced care modalities in one setting. This includes prevention and education, wound care, infection management, surgical and hospital management, research and grant development, community and regional education, and the creation of orthotics, prosthetics, and shoes. Approximately 400 patients are treated at LPS each month.

Description of care: examinations

Careful and frequent inspection of the diabetic foot is the most effective and least expensive method of preventing diabetic foot ulcers and possible LEAs. Diabetic patients at MAMC without foot-related risk conditions receive a comprehensive annual foot examination as required by the Veterans Administration/Department of Defense Diabetes Clinical Standard (18) and as recommended by the American Diabetes Association (19). Patients at MAMC with generally accepted "limb at risk" factors (19,20) are referred to the LPS. This includes patients with foot deformities, peripheral vascular disease, neuropathy, and other risk factors.

Figure 1 outlines the seven-part LPS examination. Past or current diabetic complications and treatments are noted, and current history is recorded, including walking difficulties, shoe problems, pain, smoking, use of alcohol, age, sex, weight, ethnicity, and HbA_{1c} level. Foot evaluation assesses protective sensation, musculoskeletal deformities, vascular status, and skin and nail condition. The Semmes-Weinstein 5.07 (10-g) monofilament test and the vibration sensation tuning fork test for neurological status are performed. Pedal pulses are checked, and

other noninvasive vascular tests are administered if ischemia is suspected. The patient's footwear is checked, and their knowledge of general diabetes self-care and foot care is evaluated before and after the examination. If the patient has a current foot ulcer, history of present illness is completed.

Each patient is stratified into one of three risk classifications based on the examination and history. Criteria for each strata and the associated follow-up schedule are listed in Fig. 1. Additionally, the patient is given a management plan detailing frequency of future examinations, educational counseling, diagnostic tests, footwear modification, and specialist referral, as necessary. Distribution of LPS patients across risk categories is as follows: low 37%, moderate 23%, and high 40%.

This stratification reflects the paradigm of risk assessment implemented in the LPS. Although not yet validated by clinical trial evidence, this approach may provide advantages over a "high versus low" classification. Patients with foot deformity without neuropathy are assigned a higher risk category than patients without deformity. Neuropathy will develop in some patients at moderate risk; therefore, early intervention with footwear modification, education, and surgery may be beneficial. We believe that three strata encourage more aggressive surveillance and intervention in this subset of patients. A cohort study examining these issues is currently underway at the LPS.

The most common cause of foot ulcers is a sequence of neuropathy, deformity, and minor trauma (21,22). Based on LPS data, 83% of high-risk patients have peripheral neuropathy, whereas only 4% have peripheral vascular disease and 17% have both conditions. A total of 60% of patients with peripheral neuropathy have foot deformities and 17% have a history of ulceration. Based on risk status, patients may be referred to specialists for more detailed evaluation. For example, if screening indicates possible lower extremity ischemia, consultation with a vascular surgeon is sought.

Glycemic control can reduce the incidence of neuropathy, which is the primary cause of diabetic foot ulcers (23). The importance of adequate diabetes control to reduce neuropathy and a host of other comorbidities is emphasized during patient education. Shoes can serve either a protective or a contributing role in the development of diabetic foot ulcers. Irritation caused by shoes was the primary contributing factor in 90% of neuropathic foot ulcers in one study (24). Therapeutic footwear has been shown to reduce the occurrence of new lesions in diabetic patients, although reports are mixed regarding prevention of reulceration (25–27). Nearly all patients treated at LPS have a consultation with an orthotist.

All MAMC patients with chronic disease now have a health "scorecard," a new system of patient monitoring at MAMC that allows tracking of key health status data. Patients and providers can access the data, which can be used for a number of health care objectives, including examination scheduling, monitoring of important diagnostic and preventive criteria, or analyzing health outcomes.

Description of care: treatment practices

Similar to other wound classification methods (28–31), the LPS uses a system that includes different ulcer characteristics: location, depth, shape, width, inflammation, edema, exudate quantity and quality, tissue quality, presence of vasculitis and/or cellulitis, duration, and others. Limb-threatening diabetic foot ulcers can include cellulitis extending more than 2 cm beyond the ulcer perimeter, deep abscesses, osteomyelitis, gangrene, or critical ischemia (32). As in other specialized foot care clinics, treatment priorities at the LPS are as follows: *1*) aggressive treatment of infections; *2*) diagnosis of ischemia and evaluation for possible revascularization; *3*) relief of pressure to the wound; and *4*) improvement of the wound environment with debridement, dressings, and advanced care treatments where appropriate (33).

Treatment of complicated diabetic foot ulcers can involve many pathways. After a complete ulcer evaluation, including measurements, X-ray studies, and possibly biopsy, debridement is started. The method of debridement depends on patient and wound factors, including vascular condition, medications, necrotic load, exudation, presence of infection and edema, and may vary over the course of treatment. After initial debridement (normally sharp), a culture may be obtained at the wound base. All patients with infected wounds undergo an infectious disease consultation, although the initial choice of antibiotic is empirical. Patients with wounds and peripheral vascular disease undergo a vascular surgical consultation. The infected, ischemic wound is the most difficult wound to treat at the LPS and at most clinics (34,35). Deep, infected wounds are checked for osteomyelitis by identifying direct exposure of bone or a positive "probe to bone" test. Osteomyelitis is verified with magnetic resonance imaging or leukocyte scans with indium In 111 oxyquinoline. Infected bones and joints often require resection. A wide range of off-loading options are available, including hospitalization/bed rest, wheel chair, total contact casts, extra depth shoes, and various types of boots and sandals.

Structure of care at LPS and MAMC

MAMC is a large military hospital where 360 doctors practice in a wide range of fields. Unlike private practice, MAMC presents few traditional barriers to specialist referral or to communication among specialists. Close collaboration among providers at MAMC contributes to the success of the LPS. In addition to the well-documented benefits of multidisciplinary wound care clinics (36–43), patients in a military medical setting remain within the system for long periods of time, allowing an increased level of monitoring for chronic and at-risk patients. The previously mentioned scorecard system assists in this commitment to "whole patient" care.

A podiatric surgeon has directed the LPS since the inception of the clinic. The clinic has one surgical position that rotates among three residents, as well as one research fellow, eight interns annually, and a nurse specialist and four grant-funded administrative and clinical staff.

Professional and patient education

The LPS has a broad educational program. In addition to the rotating surgical position, other residents at MAMC spend time at the LPS learning wound treatment techniques. Non-MAMC providers periodically participate in training at the LPS. Some of the external training is best described as "train-the-trainer" education, enabling providers to return to their clinics and train their colleagues.

The LPS has hosted several large interdisciplinary conferences, most notably the recent Northwest Limb Preservation Conference (March 2004). This conference brought together nationally and in-

ternationally known speakers to discuss topics related to diabetic limb preservation. A number of hands-on workshops were also included. These conferences are self-funded and place no cost burden on the institution, but they provide an excellent opportunity for both student and practicing physicians to learn, teach, and network.

The LPS participates in numerous treatment and prevention clinical trials. The patient population at the LPS is large and includes patients who are often candidates for studies of the prevention and treatment of LEAs. These investigations provide staff with knowledge of emerging treatment modalities, and patients have the opportunity to make treatment decisions that include advanced therapies in various phases of U.S. Food & Drug Administration approval. Ongoing research also creates an environment in which generation of hypotheses is encouraged. Although an active clinical research program is not a necessary component of a successful limb preservation clinic, its benefits are numerous for both patients and practitioners.

Patient education is a high priority and is provided during patient examinations. The benefit of education in reducing diabetic foot ulcers and LEAs is well documented (32,44–46). Patient awareness of foot care principles and procedures are assessed before and after examinations. Patients with diabetes at the LPS often underestimate their foot risk status. A total of 34% of patients considered at high risk after screening perceived themselves to be at low risk. General diabetes issues reviewed with patients include the diabetic disease process, glycemic control, nutritional management, and medications. Patients are advised regarding avoidance of foot trauma, proper foot hygiene, proper shoe selection, and the importance of daily foot inspection. An individualized educational plan is developed if appropriate. MAMC has a diabetic education liaison staff that assists in providing this information to patients.

Data analysis

Outcomes data for the LPS are currently limited to the incidence and type of LEAs in diabetic patients from 1999 through 2003. Although data on LEAs are available for periods before 1999, the number of patients with diagnosed diabetes enrolled at MAMC is only available since 1999. The incidence of diabetic LEAs was calculated by dividing the number of LEAs in enrolled diabetic patients, by the number of enrolled diabetic patients at MAMC for each year. Types of LEAs were compared with national averages from Centers for Disease Control and Prevention (CDC) diabetes surveillance statistics (43). Patients were selected using ICD-9-CM codes for in-patient LEA surgery on diabetic patients.

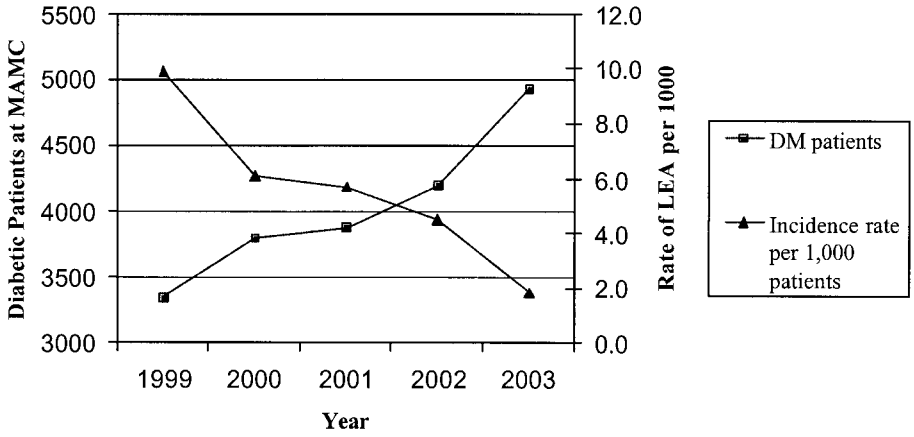

Figure 2—*Increase in diagnosed diabetic patients and decrease in LEA incidence rate at MAMC.*

RESULTS

Incidence of LEAs

Data presented include all inpatient LEAs in patients with diabetes between 1999 and 2003. During this period, the number of diagnosed diabetic patients at MAMC increased 48% from 3,340 in 1999 to 4,940 in 2003. It is not known whether the large increase in patients with diabetes at MAMC is due to changes in patient assessment or a reflection of the national trend of increasing prevalence of diabetes. Concurrent with the increase in patients with diabetes at MAMC was a decrease in the number of inpatient LEAs from 33 in 1999 to just 9 in 2003. Figure 2 shows the dramatic decrease in LEA incidence, along with the increase in number of patients with diabetes at MAMC. The incidence rate of LEAs in patients with diabetes at MAMC dropped from 9.9/1,000 to 1.8/1,000 over 5 years. Incidence of amputation is recorded for each inpatient event. Patients with more than one LEA are represented in these data once for each subsequent ipsilateral or contralateral LEA.

An additional positive outcome for MAMC patients with diabetes is the improvement in the types of LEAs compared with national averages, as shown in Table 1 (8,47). The philosophy at LPS is to react as quickly as possible to amputation indications and to salvage as much of the limb as possible. Therefore, the distribution of LEAs by anatomical level reflects a greater percentage of toe- and foot-level amputations at LPS than the national average.

Between 1999 and 2003, men comprised 76% of the patients with LEAs at MAMC. Despite being an Army hospital, only 48% of diagnosed diabetic patients at MAMC are men. Therefore, the large proportion of LEAs in men at MAMC is not only the result of patient demographics. Recent epidemiologic studies show that men are more at risk for diabetic LEAs than women (8). In the MAMC population of diabetic patients from 2000 to 2003, the relative risk of amputation for

Table 1—*Comparison of LEA levels between U.S. national averages and MAMC*

Type of amputation	Toe (%)	Foot and ankle (%)	Below knee (%)	Above knee (%)
U.S. diabetic patients (1989–1992)	40	15	25	17
U.S. diabetic patients (2000)	43	14	29	12
MAMC diabetic patients (1999–2003)	50	21	17	12

male patients (versus female patients) was 2.84 (95% CI 1.70–4.73), and this effect was stable over time, although the small number of amputations in 2002 and 2003 yields nonsignificant CIs. The most recent (2001) CDC national statistics for diabetic LEA hospital discharges by sex show that 57% are men (48). Age is another factor believed to affect amputation rates. The relative risk of amputation for patients older than 60 years of age was 2.43 (95% CI 1.45–4.06). As with sex, the age-related risk ratio was stable over time; however, in years with sparse data, the CI contained 1. Data were not available for analysis of racial differences in LEA rates among patients with diabetes at MAMC.

CONCLUSIONS — The LPS at MAMC exemplifies the benefits of a focused limb preservation team within a large multidisciplinary health care facility. The annual incidence of inpatient LEAs among patients with diabetes at the hospital has decreased 82% over the past 5 years. The 2003 LEA rate for patients with diabetes of 1.8/1,000 is lower than any found in the current literature. In addition, the types of LEAs at the LPS are at more distal anatomic levels than national averages. A total of 71% of the LEAs performed at MAMC during this period were at the foot, ankle, or toe level. The financial and quality-of-life benefits derived from these improved patient outcomes are significant. Peters et al. (49) analyzed quality of life in patients with diabetes after LEA compared with patients who had not undergone amputation and found that impairment scores in patients with toe or midfoot amputations were not significantly different fromthose in the control patients. As expected, patients with more proximal amputations were more functionally impaired than control subjects. Sex and age are both predictive of amputation; however, this study was not prospectively designed to evaluate these factors.

A decrease in the yearly number of amputations and incidence of amputation among patients with diabetes at MAMC seems to be temporally related to the creation of the LPS and its predecessor, the Foot At Risk Clinic. Although more data are necessary to establish a causal link, these data do seem to meet many criteria for causality enumerated by Bradford-Hill (50). As with most medical phenomena, however, these outcomes are likely to be associated with a number of contributing factors. Additional evidence is required to definitively demonstrate the amputation-reducing effect of the LPS and its analogues; however, these data support the hypothesis that multidisciplinary specialty wound care clinics influence the rate and anatomical distribution of limb-modifying surgeries among diabetic patients.

The apparent success of a multidisciplinary diabetic foot care clinic is not surprising. There are numerous examples illustrating the success of this concept. Implementing the organizational, coordination, and procedural elements and associated support resources for a successful foot care clinic is a formidable challenge. Many successful multidisciplinary diabetic foot care centers lack key performance measures necessary for program evaluation (51). A successful foot care team requires an energetic, dedicated, and progressive staff. The LPS has been proactive in educating its own members, other professionals, and, of course, its patients. The strong clinical research program run by the LPS assists in keeping staff abreast of advanced care practices. The structure of care at a military hospital also provides few barriers to referrals, diagnostic procedures, and treatments. Firm support from the hospital's administrative hierarchy is evidenced by the patient scorecard system and the extensive assistance from staff at the recent Northwest Limb Preservation Conference.

Future research at the LPS will address the hypotheses generated herein. The validity of the three-tiered risk structure is under evaluation, and a large outcomes study is underway to examine issues including the role of deformity in the ulcer development process, with and without neuropathy. Clinical trials of wound treatment, studies of predictors of ulceration and amputation, and outcomes research augment our capacity for informed clinical decision making. The cost and quality-of-life benefits associated with the deferment or prevention of limb-modifying surgery, especially proximal amputation, are substantial. For this reason, the preservation of limbs will remain a primary objective within the Department of Surgery and throughout MAMC.

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